

5534. Adulteration of tomato pulp. U. S. * * * v. 25 Cases of Tomato Pulp. Default decree of condemnation, forfeiture, and destruction. (F. & D. No. 7162. I. S. No. 10934-1. S. No. C-422.)

On January 20, 1916, the United States attorney for the Middle District of Alabama, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district a libel for the seizure and condemnation of 25 cases of tomato pulp, remaining unsold in the original unbroken packages at Montgomery, Ala., alleging that the article had been shipped on December 1, 1915, by A. E. Kidwell & Co., Baltimore, Md., and transported from the State of Maryland into the State of Alabama, and charging adulteration in violation of the Food and Drugs Act. The article was labeled in part: "Hartlove Brand Tomato Pulp. Made from pieces of tomatoes and trimmings. * * * Packed by Hartlove Packing Co., Baltimore, Md."

Adulteration of the article was alleged in the libel for the reason that it contained a partially decomposed vegetable product.

On April 25, 1917, no claimant having appeared for the property, judgment of condemnation and forfeiture was entered, and it was ordered by the court that the product should be destroyed by the United States marshal.

CARL VROOMAN, *Acting Secretary of Agriculture.*

5535. Misbranding of "Pulmonol." U. S. * * * v. Pulmonol Chemical Co., a corporation. Tried to the court and a jury. Verdict of guilty. Fine, \$25. (F. & D. No. 7185. I. S. Nos. 1355-h, 7266-h.)

On July 17, 1916, the United States attorney for the Eastern District of New York, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district an information against the Pulmonol Chemical Co., a corporation, doing business at Brooklyn, N. Y., alleging shipment by said company, in violation of the Food and Drugs Act, as amended, on or about October 4, 1913, and March 21, 1914, from the State of New York into the States of Massachusetts and Minnesota, respectively, of quantities of an article labeled in part, "Pulmonol," which was misbranded.

Analyses of samples of the article by the Bureau of Chemistry of this department showed that it was essentially a solution in glycerol and water of sodium benzoate, potassium, guaiacol sulphonate (thiocol), and a little strychnine, and colored with amaranth, a coal-tar dye.

It was alleged in substance in the information that the article in each shipment was misbranded for the reason that certain statements appearing on its label falsely and fraudulently represented it as a remedy for all pulmonary diseases and all forms of consumption, and as effective for improving nutrition and relieving night sweats, when, in truth and in fact, it was not. It was further alleged in substance that the article was misbranded for the reason that certain statements included in the circular accompanying the article falsely and fraudulently represented it as effective for preventing hemorrhages and breaking up all severe colds, as a cure for consumption and tuberculosis, and as a remedy for night sweats, when, in truth and in fact, it was not.

On February 8, 1917, the case came on for trial before the court and a jury, and after the submission of evidence and arguments by counsel the following charge was delivered to the jury on February 10, 1917, by the court (Chatfield, J.):

I think that the present case is in many ways one of the most serious and one of the most important matters which I have ever been called upon to submit to a jury. In the ordinary criminal case the question is whether one individual should be held to have been shown beyond a reasonable doubt to have violated something which Congress has said should constitute a crime, and the personal liberty or liability to a fine of that individual is the limit of risk in the particular case. In so far as the case may establish a doctrine, or in so far as the case may form an example, it may be used or not used—as the case may be disposed of if it is appealed or as Congress may legislate upon a matter of the same sort—when another case comes up. When a statute is passed it is made the law of the country, on which the act of one individual may be in a sense the test as to whether or not the opinion of a great many people or of a few people is correct, when the application of that test may mean the life or death, the health or sickness, of many people, and when you have the position of one man protesting for his ideas against the general opinion of those who are supposed to know about the subject. When a jury of 12 men are called upon to consider whether or not the ideas of the man as against everyone else, or nearly everyone else, are correct, or when the jury finds itself in a position of considering whether or not the opinion of the world up to the present time is correct, you have a very serious subject to consider, and the court has a very serious duty in deciding just how the matter shall be left to you and just what shall be left to you.

Now the Supreme Court of the United States, in the case from which the district attorney has just read to you, said, that it had been decided in other cases that Congress by this statute deliberately excluded the field where there are honest differences of opinion between schools and practitioners. It said that the statute did not intend to invade the domain of speculation. The Supreme Court has held in other cases that this statute, that the laws of the United States, do not attempt to decide whether or not a belief of one person or the belief of many persons is right, and that those laws do not bring up such a test in these criminal statutes. If I may use a plain illustration,

I think if at the time that the whole world believed in witchcraft one person should have advertised something that contradicted the doctrine of witchcraft, the United States Government under the Constitution and under its method of enacting law as it exists at the present time would not allow a person's liberty to be brought into jeopardy under a criminal statute by the mere decision as to whether or not witchcraft was true or false. That comes in the domain of freedom of opinion or of belief. I am inverting the case because now everyone believes that witchcraft does not exist, and no person perhaps could be found that would oppose that idea.

In the case at bar it is the opinion apparently of the medical world generally, and of most individuals, so far as they have gained their ideas from doctors and from the investigation of the doctor's statements that have been made—it is the idea of the world that tuberculosis, as has been stated, is a disease that comes from the presence of a germ or bacillus that is substantially always present and which may progress if circumstances give it the opportunity. Now, you have heard that it is not the general opinion that any particular medicine can keep away or remove this opportunity for these germs to develop in the lungs (because we are not talking about joint tuberculosis and other matters of that sort). You have heard from the testimony that if, according to the general opinion of doctors, after these germs have started their development and have proceeded upon this awful course that Mr. France has tried to explain to you, which I am not even going to try to follow, if they have gotten to the point where a person would say that one lung was gone, whatever that means, then the general impression and opinion as indicated by the testimony of the witnesses, and what has been stated to you, of the world to-day is that no medicine will either stop the going of the lung or bring the lung back from where it has gone, but that, as has been said, these germs may be stopped, that is arrested and stay inert or dead, whatever it may be, by certain treatment that removes their opportunity to continue active. Now, when you are considering whether generally everybody is right and that the medicine does not actually do the arresting (and I think that Dr. Payne told you from his standpoint the medicine itself does not act like a policeman and cause this arrest), when you consider that, and then attempt to determine who is right in forming an opinion and reaching a conclusion as to just what medicine may have to do with the conditions which will be present if fresh air and the proper amount of exercise, and the proper number of eggs and other food are taken—when you are considering just what medicine will have to do with the creation of these conditions, and just what medicine will not have to do with the creation of these conditions, and attempt to say whether one doctor is right in saying that you should have two eggs, whether another doctor is right in saying that you should have no eggs, whether one doctor is right in saying you should have no medicine, and whether the other doctor is right in saying that you should have pulmonol with those things—these matters have nothing whatever to do with this case.

This is not a case in any sense where the practice of using pulmonol is in question. It is in no sense a case whether the Pulmonol Company should sell pulmonol. It is in no sense a question whether Dr. Payne should continue to prescribe pulmonol. We have nothing to do with whether he may convert everybody to his opinion. I can say to you, as a matter of law, that if Dr. Payne is right, we should help him convert people to that opinion; that if he is right, and it is a matter of opinion, the whole world should agree with him. So, I have let him put in the testimony. I have let him state these cases to you so that you should see that, viewing the facts and viewing the patients and viewing the situation, looking at it from Dr. Knopf's standpoint, looking at it from Dr. Payne's standpoint, there is a difference of opinion, as to which the two men may be as honest in their variances as may be and they may each believe absolutely that the other is entirely wrong. I do not mean entirely wrong, because they agree on some of the conditions, but I mean, wrong in saying that the other is on the wrong track. We can leave that all out of the case, but it was necessary to let that testimony in, to allow this situation to get before you so that you gentlemen, as jurors, would not be disposing of this case on a question of opinion as to whether pulmonol may be a good medicine or not. So, as the Supreme Court has said, Congress recognizes that they would not decide between one form of religion and another, as to which may be the best assistance to the doctor in administering medicine. It would not make any difference as to whether, so far as Congress was concerned, the man's wife is a Christian Scientist, or whether the man's wife is a Roman Catholic, or a Presbyterian, or a Jew, so far as his mental make-up is concerned. If he takes a dose of Epsom

salts his mental attitude may have something to do with the situation. The doctor told you there was a psychology in this, and if the man would have greater psychology if he goes to one church and thinks of it one way and have less psychology and just as much of Epsom salts if he went to another church, you as jurors can leave that out, because Congress has left it out and it is not in the statute. Congress, as the Supreme Court says, used the words in order to leave no doubt upon that matter, that the statement must be false and fraudulent. In other words, there must be intent to deceive people so as to make them engage in commerce—that is, spend money or the equivalent of money—because they are misled and deceived, and that brings me to this statute itself and to what this case is about.

Perhaps some of you were here in some of these other cases that had to do with foods. Some of you may have been here in ordinary negligence cases where you heard something about the regulation of interstate commerce. But bear in mind that this is a criminal charge. At the outset this paper, which has been called an information—you can see that there is much paper in it. It costs more than one sheet would, as you can see, and the price of that paper might cost more today than it did a month ago, but that has nothing to do with this case—that information is merely a sheet of paper which notified the Pulmonol Company that they were to be here, because a jury was going to listen to their case; and they are here and you are hearing the case, and you must judge the case only from the evidence that has gone to you in the case, using your intelligence and the knowledge that you have gained throughout your lives in passing upon that evidence. So the Government must present evidence or else, of course, there would not be any case. The Government must show what will satisfy you beyond reasonable doubt that the defendant has done what it charges or else you can not get to the point where you could render a verdict for the Government, and therefore, of course, I charge you that as this is a criminal matter that you must weigh everything that has been said so as to see if it was proven beyond reasonable doubt that the defendant did that with which it is charged and which I shall specifically in a moment state. You have heard what does not ordinarily happen in a case. You have heard a good many more witnesses for the defendant than for the Government in this particular matter. You must take into account not how many there were or how fast each one talked nor how many words they said, but take into account what they said which is material to the issue in the case. Consider how they said it, who they are, what relation they have either to the result of the case, or to the subject matter, and use all that as light, just as you use their appearance and their intelligence and the way of saying things to throw light upon your minds in determining how much you believe, in order to decide of what you are satisfied as to all the facts as to the different things, and then see if those facts, that you find from the testimony, prove beyond reasonable doubt that the charge is made out.

This corporation, so far as we know anything about it, is supposed to be reputable. Its connection, you have heard, with the Salvation Army; that may be considered by you as something in their favor, as to honesty in their intentions, and, so far as you know anything about this company, consider whether their intent is to defraud. Doctor Payne has testified. He has told you he is the president; he has told you he is the medical officer; he has told you he is the salesman; he has told you that he does everything that is necessary for the company and therefore he has given you a chance to judge of the company's intent and its dealings in so far as he might advertise the drug of this company or the merits it had. So from that you can determine these questions of fact as to what their purpose, their knowledge, and the meaning of their acts are. And so you come down in this case to a determination not as to whether pulmonol is a good medicine, not to a determination as to whether one person is right in thinking that it will cure consumption, not to a determination as to whether other people are right in thinking that it has no effect upon pulmonary consumption, or that it has no effect as a tonic. You come down to a determination in no way of whether or not fresh air and treatment, without medicine, is the only specific. But assuming that people generally and the public who buy medicine have been of the impression that tuberculosis is to be treated only by fresh air and change of climate and food and care, then if a remedy is presented which it is said will cure tuberculosis, and if that remedy is sold to them, and if they are thereby induced to purchase the remedy, you have to consider whether or not the statements upon the bottle and upon the papers in the package in which it is sold, in the first place, accord-

ing to one paragraph of the statute, whether the package or label bears any statement, design, or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular.

Now, this statute, as I have said, was passed by Congress because they have the power to provide police regulations as to the way in which goods shall be sent from one State to another. As to how one State shall deal with another in a commercial way, Congress has the power to decide what is good; that is, what will have a beneficial effect in this matter of police regulation upon the people of one State when they are dealing with the people of another, in the sense of regulating the goods that they may exchange. So that Congress can stop the transmission of opium from one State to another, if Congress reaches that conclusion. That is a police regulation. So Congress may legislate that liquor shall be stopped in interstate traffic. Congress has the power to say that pulmonol shall not be shipped from one State to another, if Congress reaches the conclusion that pulmonol shall be prohibited in its statute. But these statutes have not gotten down to that refinement. This general statute says that no food product and no drug shall be sent from one State to another which bears upon it a false label, or a label that is misleading as to matters of fact, as distinguished from those purely of opinion, where it is made plain that it is opinion. You have heard them talk about codeine and derivatives of opium. If a medicine contains those derivatives and they are not stated, or if the preparation is incorrectly stated so that the label is misleading then Congress says that this shall not be sent from one State to another because those who purchase it would not know what they are buying. So under this first main section of the statute this defendant is charged with having on these two occasions, which are admitted, sent from the State of New York to another State packages of pulmonol that bear this language, which has been read to you, and the Government charges that some of those statements in there are false and misleading as facts as distinguished from opinion.

At the time when this law was passed, in 1912, apparently there was some necessity that came into the view of Congress for stopping the traffic in drugs where the statement on the label was not false as to the contents of the package, or not false as to what the package was or meant to be, but where the statements were false as to the effect of the package generally. The idea that Congress was considering was what is popularly known as the sale of patent medicines, or put-up drugs, as a matter of business where people buy them without knowing what they are. To come back to the illustration of liquor again. If an article was put out as a medicine and there was a statement that it would cure certain diseases, and if in fact it was a beverage which was furnished to people so that they thought it was a medicine, so that they either did not know it was a beverage or that they did not recognize its effect, and if that article could be shown to be sold because people would buy it to drink, and if it could be shown that it had no medicinal effect, then that article would come within the prohibition of this statute. Now, we might come to a long discussion as to whether alcohol and medicine had any medicinal effect. We will not discuss now whether a person might be charged with having misbranded an article because he said it contained 15 per cent of alcohol and the alcohol would help cure a cold, or a thirst, whichever it might be. That would be a matter of opinion. But if he stated that alcohol was a cure for baldness, or if he stated that the bottle of something or other was a cure for baldness; and all it proved to be was that it was good for drink, then it could be stopped under this statute.

Now, I am using illustrations that do not come very close perhaps to this, but I do not want to come too close, because I am going to leave the question to you. The question is what the effect of this particular article may be as viewed from the statement of facts, distinguished from those of opinion. So in 1912 Congress, in order to reach the kind of cases that I have referred to, added the section that said if the label contained anything which was false or misleading—in fact that was already in the statute—and added this: If the package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic power of such article, or any of the ingredients or substances contained therein, and if that statement is false and fraudulent, then it would be treated as constituting a crime, in the same way as before, when the statute said “if it contained misstatements of fact.” So that we have here a change, of course. If you find it proven beyond reasonable doubt that this label contains in it any statement of fact (as distinguished from a statement of opinion, or as distinguished from a statement of conclusion as

to the recovery of a patent) which is false, then it would be within the main part of the statute. Then, if you should find that the label contains any statement as to the curative or therapeutic effect—from our standpoint therapeutic and curative are substantially the same—and if that statement is not only false; that is, if you find it is not based on fact, but if the persons who made the statement knew or should have known or must have known that the statement was false, and if they put that there for the sake of giving out a false statement and of making a statement to people which would cause them to buy something because they did not know the truth, then that would come within the second portion of the law, and if the Government proves that beyond reasonable doubt, your verdict should be guilty.

Now, this case, as has been said, is not a test as to whether or not the Pulmonol Company can do business or whether it can sell this medicine. It really is only a test as to whether or not the particular label that is upon the medicine at the present time is misleading and intentionally false and fraudulent, and whether it contains statements that are contrary to fact. If so, then, if proven beyond reasonable doubt that this was so, the defendant would be liable to the penalty of having to correct its label so that no one would be misled in that respect, and be punished in such a way as the court might see fit, according to the amount of intent in the misstatements that the package contained. It is for that purpose that Dr. Payne was notified by the Department to tell them what he knew about the contents of the article and the accuracy of the statements upon the article. If there had been a provision there that the liquid in that bottle was red, white, and blue in color, and it proved to be all red, and Dr. Payne had gone down there and they had said, "Why do you say it is red, white, and blue?" and he said, "Well, it is. When you mix it, it is first white, and then blue, and then red. I did not intend to give the impression that it was red, white, and blue all at once," the Government would have said, "Well, you should say it is first white, and then blue, and then red, and as long as it is red it is in a condition in which people can take it." He could have rebranded his label in that respect and the Government would consider whether or not the company should be prosecuted for the use of the previous label, or whether it was something that did not necessarily mean that a person should be charged criminally with having put out something that is fraudulent. So, in that way this matter was called into discussion. The situation behind it, as to this disagreement between Dr. Payne and the other doctors, as to his standing in this society which is formed by physicians, and in which they attempt to regulate or control the action of those who are practicing as doctors, let us entirely leave out. The question whether you agree with them, or disagree with them, their methods, or their actions in dealing with some one who runs counter to their ideas, has nothing to do with this case, unless it affects the credibility of one of the witnesses, or unless it shows interest or bias on the part of one of the witnesses so that his statements here are not to be taken for their face value. You jurymen can weigh all those things so as to see whether a man is so certain that a person is a wrongdoer that he would not listen to anything properly that might be said in the man's favor or might be true when said about a man. On the other hand, a man who is being criticized may feel that the others were wrong to such an extent that he will not entirely give full consideration to what a third party may be doing without having the slightest interest in the difficulties between the first two.

So far as the Government is concerned, you may start with the assumption that the district attorney, and in this case the Government, in presenting this question leaves to you in no way an opportunity or idea of siding with the other doctors or with Dr. Payne. That has nothing whatever to do with the issue. Whether the Department of Agriculture learned Dr. Payne's analysis and suggested to the chemists that they look it over and see if they could find something they had not found before has nothing whatever to do with whether or not the statement on the label is all right; it only has to do with whether or not the chemists followed that suggestion. You have nothing to do with the question whether the officers of the Government may have been attempting to help the other doctors and hurt Dr. Payne (you can assume that they have been so misguided and blinded that they are not fair to one set or the other); but the thing for you to consider is whether or not their accuracy of observation in their analysis of the product is correct, as you have heard all the testimony, and then consider whether their analysis is correct. They have told you what is in the product. Then see whether this label contains

anything that is false, that is, in the sense of inaccuracy or misstatement as to what the medicine is made of or as to what it is. For instance, if it said it was a solid and not a liquid you could pass on that as a question of fact. If it said that it was beneficial in certain diseases, and the bottle was empty, you could pass on it as to whether it would be beneficial to take nothing where they said you must take something. If it were proven that the bottle contained merely water and they told you that the patient must take something, why then (unless they could tell you that this psychology entered in so that if they took sugar instead of medicine and the sugar was coated with pink, it would be healthful merely because the patient thought they were getting something) then you could take into account that the statement would be false, when it claimed that the medicine was healthful; but, if the statement is that this pink-coated sugar contains quinine, and it does not contain it, then you have a question of fact.

You have got to be very careful all the way through here to dispose on one side of all the matters of opinion and on the other side of all questions of fact. Dr. Knopf has gone through this label and in response to my question has taken up clause by clause the different statements of what is in the medicine and of its action. In most respects, perhaps in all respects, as he said, the sentences as composed of words in the English language and as stating something with relation to the contents or to matters that are used as medicine, are true. He differs when he gets to the proposition that this particular medicine is of any effect as a medicine in tuberculosis cases, and there is a question of fact for you. If the medicine has no effect and if it is sold merely because people are anxious to buy a remedy, and if they deceive themselves into thinking that remedy is doing them good (even if they thereby help themselves); or if the remedy, because they take care of themselves, does not have any effect of itself; in other words, if it is just the same as if there was so much water in the bottle and if it was sold with the intent of making people pay for water, that is, pay for an inert substance and induces them to exercise the psychology of curing themselves, and if this label you find contains a statement of a cure that does not cure as a matter of fact, with the understanding that people would get in buying it, why then the label is false and misleading, and you would consider whether you are satisfied beyond reasonable doubt that under this third section of the statute it was intentionally made false and misleading in that way.

Now, the information has two counts, one relating to the package that was sent to Boston, Mass., on or about October 4, 1913, and the other which was sent to St. Paul, Minn., on or about March 1, 1914. Of course, as I have already charged you, it would be interstate commerce to sell a bottle of medicine to some one in either Boston or St. Paul, to send it from Brooklyn to comply with the sale. There is no dispute as to the language that is upon the packages because they have been submitted to you. The counts have not been separated into a charge as to whether this is intentionally false and fraudulent as to distinguish it from merely misleading or false. In fact I have tried to distinguish that by telling you that if the Government satisfies you beyond reasonable doubt that the intent was to put out something that was false and misleading with the idea of deceiving for the purpose of disposing of it as an article of use, not necessarily of sale, then, of course, the matter would come within the language of the information. If you find that there was no intentional fraud, no intentional presentation of a false statement, and if you should still find that the language upon the package was false and misleading as to facts as distinguished from opinion, it would still come within the language of the statute. If the Government should satisfy you as to that beyond reasonable doubt, the charge would still be made out in that sense. And as I told you, it is all a question of whether you find as a fact one or two of these matters. One, that this label was intentionally false and fraudulent and sent out for the purpose of deceiving, as distinguished from an honest belief that it was helpful and that the statements made were true. The other point is, if you find that the statements upon the paper itself state as facts what is not so in any material sense or particular, according as you determine those questions (of course, recognizing the proposition that if any witness willfully deceives you here within the court room, it is within your power to pay so much attention to what he says as you see fit, weighing all the testimony) then see if the precise charge under this information is proven beyond reasonable doubt, and do not speculate upon these matters of medical science; do not determine

for yourselves whether or not you want to buy this medicine or have somebody use it, or whether you would try it as a last resort. Keep that out of the case. Simply see whether the defendant has done something that brings it within this statute and whether that is shown beyond reasonable doubt.

The Government requests me to charge:

(1) It is unnecessary for the Government to prove that all the statements on the label or booklet or circular were false and fraudulent. If you believe from the evidence that any one statement as to the curative or therapeutic properties of this compound was false in fact and that the defendant knew that it was false, then you may find the defendant guilty. I so charge.

(2) If you believe from the evidence that as to any one of the ailments for which this compound is recommended by the label or booklet or circular and which is set forth in the information this compound would have no beneficial effect whatever, and the defendant knew this, you may find the defendant guilty. In the way that I have defined fraud I do charge that yes. If the defendant sent these out knowing that he was making a false statement, that would be a fraud.

(3) If you believe from the evidence that any one of the therapeutic claims as to the effect of this compound upon all pulmonary diseases, for all forms of consumption, for hemorrhages or for night sweats, was false and was made by the defendant with a reckless and wanton disregard as to whether it was true or false, you may find the defendant guilty. I so charge.

(4) If you believe from the evidence that any one of the therapeutic statements upon the label or booklet or circular as set forth in the information was partly true, but was so artfully worded as to convey a meaning as to the compound's therapeutic properties which was wholly false, and that the label and booklet and circular was so worded for the purpose of deceiving the public, then that statement would be false and fraudulent, and you may find the defendant guilty. I so charge. If this paper or label was made up in such a way that people would get the idea of false facts as distinguished from either a correct or incorrect opinion of the person making the statement, if that paper was gotten up so as to present false facts to people or to make them believe things were false as facts as you find them, and if sold and put on the market for the purpose of selling by means of false statements of facts, that would bring it within the section.

Now, Dr. Payne, if you think that I have stated the matter incorrectly from either standpoint of the law or of the testimony, you want to get it on the record now.

Dr. PAYNE. I have nothing to say.

The jury thereupon retired and after due deliberation returned a verdict of guilty, and on March 26, 1917, the court imposed a fine of \$25.

CARL VROOMAN, *Acting Secretary of Agriculture.*